

AMENDMENTS TO THE CLAIMS

A complete list of claims as currently amended follows:

1. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form comprising:
 - (a) a controlled release core consists essentially of a biguanide comprising an antihyperglycemic drug and at least one pharmaceutically acceptable excipient.
 - (b) a seal coat applied to the controlled release core; and
 - (c) an immediate release thiazolidinedione derivative containing coating applied to the seal coating.
2. (original) The dosage form of claim 1 wherein said controlled release core is an osmotic tablet.
3. (currently amended) The dosage form of claim 2 wherein the osmotic tablet consists essentially of comprises:
 - (a) a core consisting essentially of comprising:
 - (i) 50-98% of said biguanide antihyperglycemic drug;
 - (ii) 0.1-40% of a binding agent;
 - (iii) 0-20% of an absorption enhancer; and
 - (iv) 0-5% of a lubricant;
 - (b) optionally a seal coat surrounding the core; and
 - (c) a semipermeable membrane consisting essentially of comprising:
 - (i) 50-99% of a polymer;
 - (ii) 0-40% of a flux enhancer and
 - (iii) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the biguanide antihyperglycemic drug.
4. (currently amended) The dosage form of claim 1 wherein said antihyperglycemic drug is a biguanide is metformin hydrochloride and the thiazolidinedione derivative is pioglitazone hydrochloride.
5. (currently amended) The dosage form of claim 1 ~~4~~ wherein said biguanide is selected

from the group consisting of metformin, phenformin, buformin or pharmaceutically acceptable salts, isomers or derivatives thereof.

6. (original) The dosage form of claim 1 wherein said thiazolidinedione derivative is troglitazone, rosiglitazone, pioglitazone, ciglitazone or pharmaceutically acceptable salts, isomers or derivatives thereof.
7. (currently amended) The dosage form of claim 1 wherein the release of the biguanide drug is not regulated by an expanding polymer ~~said core is substantially free from any gelling or expanding polymer~~.
8. (currently amended) The dosage form of claim 1 wherein said controlled release of said biguanide antihyperglycemic drug provides a Tmax of 8-12 hours.
9. (original) The dosage form of claim 1 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-12 hours.
10. (original) The dosage form of claim 9 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-4 hours.
11. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form comprising:
 - (a) a controlled release core ~~comprising an antihyperglycemic~~ consisting essentially of a biguanide drug and at least one pharmaceutically acceptable excipient; and
 - (b) a seal coat applied to the controlled release core; and
 - (c) an immediate release thiazolidinedione derivative containing coating applied to the seal coating controlled release core comprising:
 - (i) a thiazolidinedione derivative; and
 - (ii) a binder;wherein the immediate release coating is applied to the seal coating controlled release core using a solvent mixture comprising water and an organic solvent.
12. (original) The dosage form of claim 11 wherein said controlled release core is an osmotic tablet.
13. (currently amended) The dosage form of claim 12 wherein the osmotic tablet

consists essentially of comprises:

- (a) a core consisting essentially of comprising:
 - (i) 50-98% of said biguanide antihyperglycemic drug;
 - (ii) 0.1-40% of a binding agent;
 - (iii) 0-20% of an absorption enhancer; and
 - (iv) 0-5% of a lubricant;
- (b) optionally a seal coat surrounding the core; and
- (c) a semipermeable membrane consisting essentially of comprising:
 - (i) 50-99% of a polymer;
 - (ii) 0-40% of a flux enhancer; and
 - (iii) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the biguanide antihyperglycemic drug.

14. (currently amended) The dosage form of claim 11 wherein said antihyperglycemic drug is a biguanide is metformin hydrochloride and the thiazolidinedione derivative is pioglitazone hydrochloride.
15. (currently amended) The dosage form of claim 11 14 wherein said biguanide is selected from the group consisting of metformin, phenformin, buformin or pharmaceutically acceptable salts, isomers or derivatives thereof.
16. (original) The dosage form of claim 11 wherein said thiazolidinedione derivative is troglitazone, rosiglitazone, pioglitazone, ciglitazone or pharmaceutically acceptable salts, isomers or derivatives thereof.
17. (currently amended). The dosage form of claim 11 wherein the release of the biguanide drug is not regulated by an expanding polymer said core is substantially free from any gelling or expanding polymer.
18. (currently amended) The dosage form of claim 11 wherein said controlled release of said biguanide antihyperglycemic drug provides a Tmax of 8-12 hours.
19. (original) The dosage form of claim 11 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-12 hours.

20. (original) The dosage form of claim 19 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-4 hours.

21. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form comprising:

(a) a controlled release core consisting essentially of a biguanide comprising an antihyperglycemic drug and at least one pharmaceutically acceptable excipient; and

(b) a seal coat applied to the controlled release core; and

(c) an immediate release thiazolidinedione derivative containing coating applied to the seal coat controlled release core comprising:

(i) a thiazolidinedione derivative;

(ii) a binder;

(iii) a surfactant; and

(iv) a pore former;

wherein the immediate release coating is applied to the seal coat controlled release core using water, an organic solvent or a solvent mixture comprising water and an organic solvent.

22. (original) The dosage form of claim 21 wherein said controlled release core is an osmotic tablet.

23. (currently amended) The dosage form of claim 22 wherein the osmotic tablet consists essentially of comprises:

(a) a core consisting essentially of comprising:

(i) 50-98% of said biguanide antihyperglycemic drug;

(ii) 0.1-40% of a binding agent;

(iii) 0-20% of an absorption enhancer; and

(iv) 0-5% of a lubricant;

(b) optionally a seal coat surrounding the core; and

(c) a semipermeable membrane consisting essentially of comprising:

(i) 50-99% of a polymer;

(ii) 0-40% of a flux enhancer; and

(iii) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the biguanide antihyperglycemic drug.

24. (currently amended) The dosage form of claim 21 wherein said antihyperglycemic drug is a biguanide is metformin hydrochloride and the thiazolidinedione derivative is pioglitazone hydrochloride.

25. (currently amended) The dosage form of claim 23 ~~24~~ wherein said biguanide is selected from the group consisting of metformin, phenformin, buformin or pharmaceutically acceptable salts, isomers or derivatives thereof.

26. (original) The dosage form of claim 21 wherein said thiazolidinedione derivative is troglitazone, rosiglitazone, pioglitazone, ciglitazone or pharmaceutically acceptable salts, isomers or derivatives thereof.

27. (currently amended) The dosage form of claim 21 wherein the release of the biguanide drug is not regulated by an expanding polymer said core is substantially free from any gelling or expanding polymer.

28. (currently ameded) The dosage form of claim 21 wherein said controlled release of said biguanide antihyperglycemic drug provides a Tmax of 8-12 hours.

29. (original) The dosage form of claim 21 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-12 hours.

30. (original) The dosage form of claim 29 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-4 hours.

31. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form consisting essentially of:

(a) an osmotic tablet core wherein a osmotic tablet consists essentially of:

(i) a core consisting essentially of comprising:
(I) 50-98% of metformin or a pharmaceutically acceptable salt;
(II) 0.1-40% of a binding agent; and
(III) 0-20% of an absorption enhancer;

(ii) optionally a seal coat surrounding the core; and

(iii) a semipermeable membrane consisting essentially of comprising:

- (I) 50-99% of a polymer;
- (II) 0-40% of a flux enhancer and
- (III) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the metformin;

(b) ~~optionally~~ a seal coat applied to the osmotic tablet core

(c) an immediate release thiazolidinedione derivative containing coating consisting essentially of :

- (i) a thiazolidinedione derivative selected from the group consisting of troglitazone, rosiglitazone, pioglitazone, ciglitazone or pharmaceutically acceptable salts, isomers or derivatives thereof.; and
- (ii) a binder; and
- (iii) ~~a surfactant wherein the immediate release coating is applied to the seal coat that is applied to the osmotic tablet core core or sub-coated~~ core using a solvent mixture comprising water and an organic solvent and wherein the dosage form provides a Tmax of 8-12 hours for the metformin and a Tmax of 1-4 hours for the thiazolidinedione derivative.